LEiSEGANG

ELECTROSURGICAL GENERATOR USER MANUAL

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I. GENERAL INTRODUCTION

INTRODUCTION

Electrosurgical generators described in this manual are designed to provide the three most significant electrosurgical effects: cutting, desiccation, and fulguration. Solid state design provides monopolar output in this generator.

The monopolar outputs are designed with the capability of delivering smooth cutting, cutting with increasing degrees of homostasis, and fulguration with a minimum of cutting.

This manual is intended as a user's guide only.

SPECIFICATIONS

Dimensions (WxHxD)	15x5.5x15
Weight	25 lbs, 11.4 kilograms
Voltage	115/220 VAC, 50/60 Hz
Cooling	fan
Fuse	4 Amp./115 VAC, 2 Amp./220 VAC
RMS Current	5 Amp max.
Fundamental Frequency	450 kHz
Rated Load	300 Ohms
Output Power	
• Cut, Blend 1, Blend 2	10 - 120 Watts
• Coag 1, Coag 2	10 - 80 Watts
Input Voltage Tolerance	±10% from nominal

II. SAFETY

CONTRAINDICATIONS

There are no known absolute contraindications to the use of electrosurgery. Use of electrosurgery in the presence of external or internal pacemakers and monitoring equipment may require special considerations.

GENERAL PRECAUTIONS

The safe and effective use of electrosurgery is dependent, to a large degree, upon factors solely under the control of the operator. It is important that the operating instructions supplied with this electrosurgical equipment be read, understood and followed.

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Electrosurgery utilizes a radio frequency to cut and coagulate tissue and is inherently unsafe for use in the presence of flammable anesthetics or near flammable fluids or objects. Precautions must be taken to restrict flammable materials from the electrosurgical site, whether they are present in the form of an anesthetic skin preparation agent, or are generated by natural processes within the body cavities, or originate from surgical drapes or other materials.

Electrosurgical units should be used with caution in the presence of internal or external pacemakers. Interference from the electrosurgical current can cause a pacemaker to enter an asynchronous mode or can Shock the pacemaker effect entirely. When questions arise, consult the pacemaker manufacturer and/or a hospital cardiology department.

While using electrosurgery during a surgical procedure, the patient should not be allowed to come into direct contact with grounded metal objects (surgical table frame, instrument table, etc.).

Electrodes and probes found on monitoring, stimulation, and imaging devices can provide a path for high frequency current, even if those electrodes and/or probes are isolated at 60Hz, insulated, and/or battery operated. The risk of an electrosurgical burn can be reduced but not eliminated by placing the electrodes or probes as far away as possible from the electrosurgical site and the patient return electrode. Protective impedance (resistors of RF inductor) installed in the monitoring leads may reduce the risk of such burns. Needles should not be used for monitoring electrodes during electrosurgical procedures.

When an electrosurgical unit is activated, the conducted and radiated electrical field may interfere with other electronic medical equipment (such as monitors) . Provide as much distance between the monitor and the electrosurgical generator as possible to minimize interference paths. Skin-to-skin contact (for example, between the arms and the trunk of the patient) should be avoided by the placement of two to three inches of dry gauze. This will reduce the potential for alternate site burns.

ELECTROSURGICAL GENERATORS

Danger: Explosion hazard. Do not use in the presence of flammable anesthetics.

Warning: Hazardous electrical output. This equipment is for use only by qualified personnel.

Warning: The activation tone is an important safety feature. DO NOT turn down to an inaudible level.

Caution: Electrosurgical generators are not rated for continuous duty operation. (Maximum on time at a power setting of 120 watts cut, or 80 watts coag is one minute).

Caution: This equipment must be operated by a qualified practitioner only.

Caution: Electrical shock hazard. DO NOT remove cover. Refer to authorized personnel for service.

Output power settings should be as low as possible while performing any surgical procedure. Prior to making large power setting increases beyond what is considered "normal" during a procedure to maintain surgical effect, the active and patient electrodes should be closely examined to assure proper connection and/or contact.

Failure of the electrosurgical Equipment to produce the desired effect at otherwise normal power settings may indicate faulty application of the patient return electrode or failure of an electrical lead. DO NOT increase power output settings before checking for defects in the leads or misapplication of the return electrode. Effective contact between the patient and return electrode must he verified if the patient is repositioned after the initial application of the return electrode.

The electrical cord of the generator should be connected to a properly grounded receptacle. Extension cords and/or adapter plugs should not be used.

Refer servicing to qualified personnel or contact Leisegang Medical, Inc.

ACTIVE ACCESSORIES, DISPOSABLE, PATIENT RETURN ELECTRODES

Warning: Keep active accessories away from the patient when not in use.

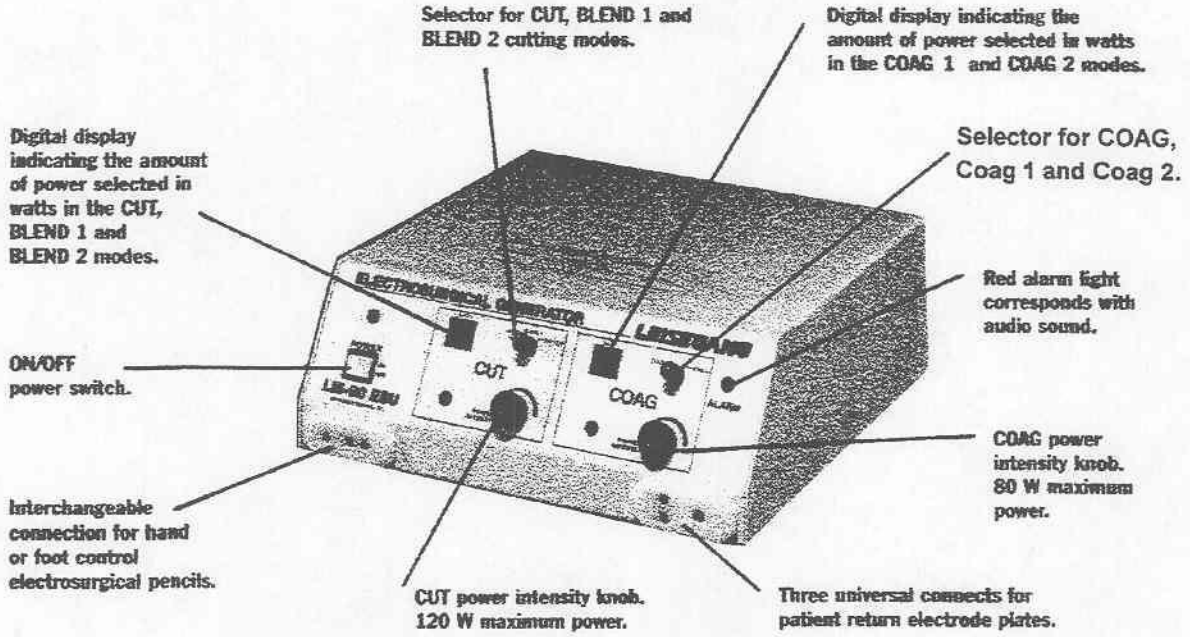
Caution: Accessories labeled as "disposable" are **SINGLE USE ONLY**. Do not reuse or resterilize.

PATIENT RETURN ELECTRODES

A critical element in the safe use of Monopolar electrosurgery is the proper placement of the patient return electrode. To avoid radio frequency burns beneath the patient return electrode, follow all directions for the placement and removal of the return electrode as supplied on the product package.

Warning: Never cut the patient return electrode to reduce size.

III. FEATURES


Selector for CUT, BLEND 1 and BLEND 2 cutting modes.
Digital display indicating the amount of power selected in watts in the COAG 1 and COAG 2 modes.
Digital display indicating the amount of power selected in watts in the CUT, BLEND 1 and BLEND 2 modes.
Selector for COAG, Coag 1 and Coag 2.
Red alarm light corresponds with audio sound.
ON/OFF power switch.
COAG power intensity knob. 80 W maximum power.
Interchangeable connection for hand or foot control electrosurgical pencils.
CUT power intensity knob. 120 W maximum power.
Three universal connects for patient return electrode plates.
CUT
COAG

Refer to Front/Rear panel of the LM-90 ESU for specific controls, indicators, alerts and receptacles.

1. POWER (on/off)

This will turn the unit power on, and will be indicated by the green LED over the switch. NOTE: This switch should be turned off to change electrodes. Turning the power back on will return the unit to the same selected power.

2. MODE SELECTORS

2.1 CUT

2.1.1 PURE CUT

Selects pure cut with lowest level of hemostasis.

2.1.2 BLEND 1:

Selects cut with minimum hemostasis.

2.1.3 BLEND 2:

Selects cut with maximum hemostasis.

2.2 COAG

2.2.1 COAG 1:

Is a low Voltage Coag

2.2.2 COAG 2:

Is a normal Voltage Coag

3. CUT POWER INTENSITY

Turning the knob clockwise will increase the selected power. The power intensity knob allows the adjustment from 10 Watts minimum to the maximum of 120 Watts. **Note:** The unit does not adjust or turn on below 10 Watts, for safety reasons.

4. CUT POWER DISPLAY

The digital power setting three digit display is visible on the left of the generator. The number displayed indicates the nominal power, in watts, which will be delivered to the patient when the mode is activated.

5. CUT MODE INDICATOR

The Amber LED will light when the cut mode is activated with either the foot switch or the hand switch controls.

A continuous medium pitch tone will be heard while the cut made is activated with either the foot switch or the hand switch controls.

6. COAG POWER INTENSITY

The power intensity knob allows the adjustment from 10 Watts minimum to the maximum of 80 Watts. Note: The unit does not adjust or turn on below 10 Watts for safety reasons.

7. COAG POWER DISPLAY

The digital power setting two digit display is visible on the right of the generator. The number displayed indicates the nominal power, in watts, which will be delivered to the patient when this mode is activated.

8. COAG MODE INDICATOR

The Blue LED will light when the coag mode is activated with either the foot switch or the hand switch controls.

A continuous low pitch tone will be heard while the coag mode is activated with either the foot switch or the hand switch controls.

9. ALARMS

The red LED will illuminate when the LM-90 ESU senses an alert condition such as those listed below.

9.1 CROSSKEY

This will be indicated with a continuous red LED and a pulsing high pitch tone. A crosskey is an indication that the generator cannot determine which mode the user is trying to select. Pressing the cut and coag switches simultaneously on the hand control and/or foot switch will result in this alarm.

9.2 RETURN FAULT INDICATOR

This will be indicated with a continuous red LED and a pulsing high pitch tone.

This will occur if the LM-90 ESU senses that a significant proportion of RF current cannot be returned to the generator through the patient return pad. This is also known as a Ground Fault Interrupt. The generator will defeat the RF output as long as the indicator is on.

10 RECEPTACLES

10.1 FRONT PANEL

10.1.1 PATIENT RETURN ELECTRODE RECEPTACLE

There are two types of connectors on the front of the LM-9O ESU. They will accept most types of standard patient and dual-section return pads.

The front jacks also make a convenient test point for a biomedical technician to test the generator.

10.1.2 HAND SWITCH

This receptacle will accept 3-pin hand switching active accessories of standard 1-pin accessories which can be activated by the foot switch. Cut and Coag modes may be activated at this Receptacle. The hand switching pencil can be foot switch activated when connected to this jack.
Note: When using a 1-pin foot switch accessory the pin must be connected to the port labeled 'ACTIVE.'

10.2 REAR PANEL

10.2.1 FOOT SWITCH RECEPTACLE

This 3-pin receptacle will accept the dual foot switch control that is available from Leisegang Medical Inc.

10.2.2 AUDIO VOLUME CONTROL

The volume of the Cut and Coag audio tones produced when the generator is active may be adjusted with this control. The Alarm tones are also adjusted. **Note:** The tones can be reduced but not eliminated. The activation tone is an important safety feature. **Do Not** turn down to an inaudible level.

10.2.3 POWER CORD

The line cord is terminated in a 3-pin plug and should be connected to a properly grounded receptacle.

IV. ELECTRICAL INSPECTION

To assure that this electrosurgical equipment is working properly the following electrical inspection should be done before each use. This inspection is designed to test the electrical safety features of this unit. If there is a failure of the device to perform in any one segment of this inspection, the unit should be shut down and a service representative should be contacted.

The electrical leads including the patient plate (return electrode) leads, the active electrode (electrosurgical pencil) leads, as well as those of the footswitch and power cord, should be inspected before each use. Make suite that insulation is not cracked or broken.

Test equipment required: Foot switch (if applicable) Hand switchable Pencil Accessory.

1. Plug power cord into rear panel mains connect. Plug power cord into rounded wall receptacle.
2. Plug hand switch accessory into front panel active connect.
3. Plug the patient plate into the front panel dispersive connect, if patient plate is not attached to patient the connection between the to pads must be shorted to disable the return fault alarm (a paper clip between pads will accomplish this task).
4. Turn CUT and COAG power intensity knobs all the way counter clockwise.
5. Press the power switch On. The green indicator light should light.
6. Turn the cut and coag power intensity display to 10 Watts.
7. Press the yellow CUT button on hand switch. Amber CUT indicator light should light and a medium pitch audio indicator should sound.

8. Press the blue COAG button on hand switch. Blue COAG indicator light should light and a low pitch audio indicator should sound.
9. Press both CUT and COAG buttons on hand switch simultaneously, producing a CROSS KEY situation. Red alarm light should light and the pulsing high pitch audio indicator should sound.
10. Plug in the foot switch to the rear panel of the generator.
11. Press left foot pedal. Amber CUT indicator light should light and a medium pitch audio indicator should sound.
12. Press right foot pedal. Blue COAG indicator light should light and a low pitch audio indicator should sound.
13. Press both foot pedals simultaneously, producing a CROSS KEY situation. The red alarm light should light and the high pitch audio indicator should sound.
14. Press either CUT or COAG button on the activating handswitch together with either the right or left foot pedal control, which will produce a CROSS KEY situation. The red alarm light should light and the pulsing high pitch audio indicator should sound.
15. Remove the patient plate from the front connector, producing a RETURN FAULT. The red alarm indicator light should light and a pulsing high pitch audio indicator should sound.

V. MAINTENANCE/SERVICE

The LM-90 ESU should be put on a twice yearly maintenance/service program. The unit should be tested for calibration and safety as per the SERVICE MANUAL by a qualified representative or BIO-MED technician.

VI. GENERATOR SET-UP PROCEDURE:

Plug the generator into a grounded receptacle of the proper voltage and frequency(extension cords and/or adapter plugs should not be used).

PATIENT RETURN ELECTRODE APPLICATION:

To apply a patient return electrode to the patient, select a well vascularized, convex skin surface which is in close proximity to the surgical site. Avoid scar tissue, bony prominence, adipose tissue and areas where fluid may pool. Shave, clean, and dry the application site as needed.

For correct application and removal of the patient return electrode, follow all instructions for use found on the product packaging as well.

UNIT OPERATION

SELECTING MODES AND POWER LEVELS FROM LEFT TO RIGHT

Turn the unit power on using the power switch on the front panel

- Select the type of "cut" mode desired.
- Select the amount of "cut" power desired.
- Select the type of "coag" mode desired.
- Select the amount of "coag" power desired.

To prevent inadvertent activation, turn the unit power off to insert electrode or to change selected electrodes. The unit will remain at the selected powers as long as the power controls have not been moved. **Note**: There is no long start-up time incorporated Into the LM-90 ESU.

While the unit is off, connect appropriate accessories to the generator (active accessory, foot switches, return electrode, etc.)

After accessories are connected, the unit power should be returned.

RETURN FAULT/GPI PREVENTIVE MEASURES

Assure quality of insulation between operating room table and patient by placing one or two inches of padding between the patient and all metal parts(including O.R. table, head restraints, metal rails, retractors, stirrups etc.). Stools used by operation surgeons should also be adequately padded.

Use of only low impedance patient return electrodes, such as the electrodes supplied by Leisegang Medical Inc.

Older model ECG monitors may contribute to ground fault interrupt alarms. Be prepared to disconnect the ECG monitor in the event the GFI alert occurs.

POWER CHANGES

The output power setting should not be changed while the unit is activated. To change the selected power the surgeon should stop treating and release the activating key, then the power can be adjusted safely.

RECOMMENDATIONS DURING SURGERY

Keep power setting as low as possible to enhance patient and user safety.

Remove eschar build-up from electrodes to maximize surgical effect.

Avoid unnecessary and prolonged activation of the generator to reduce the possibility of alternated site burns which may be caused by RF leakage currents. If a higher than

normal power setting is required, check patient return electrode and generator connecting cables for proper application and/or continuity.

When multiple accessories are used, keep lead wires separate. To reduce cross-coupling, do not twist, bundle, or clamp together.

TROUBLE SHOOTING

PROBLEM	SOLUTION
Unit does not turn on.	Check to insure the power cord is properly plugged into wall and unit
	Check both fuses in back of unit.
	Check that outlet is supplying power.
Pulsing high pitch tone.	Make sure patient return pad is plugged into front of unit
	Insure the return pad is properly attached to patient.
	Make sure that the Coag and Cut activation on foot and/or hand switch are not activated at same time.

In the event of other problem or questions contact the Service Department at:

Leisegang Medical Inc.
6401 Congress Ave. Suit 160
Boca Raton, FL 33487
Ph. 800-448-4450
561-994-0202
Fax 561-994-0962

SERVICE

Service should be done by qualified personnel only. Contact the Leisegang Service department at the number below concerning questions on maintenance or repair.

Leisegang Medical Inc.
6401 Congress Ave. Suit 160
Boca Raton, FL 33487
Ph. 800-448-4450
561-994-0202
Fax 561-994-0962

Note: It is strongly recommended that the LM-90 ESU generator be returned to Leisegang Medical at least once a year for calibration and maintenance.